

CHAPTER 41 - HEALTH: EPIDEMIOLOGY

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0900 - BIOLOGICAL AGENT REGISTRY

10A NCAC 41A .0901 GENERAL

The biological agent registry established by G.S. 130A-149 is administered by the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915.

*History Note: Authority G.S. 130A-149;
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003.*

10A NCAC 41A .0902 BIOLOGICAL AGENTS TO BE REPORTED

The biological agents that shall be reported to the registry shall be those agents listed as select agents in 42 C.F.R. Part 72, Appendix A which is adopted herein by reference including subsequent amendments and editions. Copies of this federal provision may be inspected at and copies obtained from the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915 at a cost of ten cents (\$.10) per page at the time of adoption of this Rule.

*History Note: Authority G.S. 130A-149;
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003.*

10A NCAC 41A .0903 WHEN TO REPORT

A person possessing and maintaining a listed biological agent on the effective date of these Rules shall make a report within 45 days of the effective date of these Rules. A person who does not possess and maintain any listed biological agents on the effective date of these Rules shall make a report within seven days of receipt of such agents. A person shall make an amended report within seven days of any change in the information contained in the report. A person shall make a report within 24 hours of any suspected release, loss or theft of any listed biological agent.

*History Note: Authority G.S. 130A-149;
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003.*

10A NCAC 41A .0904 WHAT TO REPORT

The report shall be made on a form created by the Department and shall identify the listed biological agents possessed and maintained at the facility; shall specify the use of the agents for vaccine production, research purposes, quality control or other use; shall indicate the form of the agents; shall identify the physical location of the laboratories and the storage areas; and shall identify the person in charge of the agents.

*History Note: Authority G.S. 130A-149;
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003.*

10A NCAC 41A .0905 EXEMPTION FROM REPORTING

A person who detects a listed biological agent in a clinical or environmental sample for the purpose of diagnosing disease, epidemiological surveillance, exposure assessment, reference, verification or proficiency testing, and who discards the agent within 14 calendar days of receiving notice of the completion of confirmation testing, or discards the agent within 14 calendar days of using the agent for reference, verification or proficiency testing, is not required to make a report.

*History Note: Authority G.S. 130A-149;
Temporary Adoption Eff. January 10, 2002;
Eff. April 1, 2003.*

10A NCAC 41A .0906 SECURITY

All persons possessing and maintaining a listed biological agent must demonstrate compliance with all safeguards contained in the 42 C.F.R. Part 72 and the Rules promulgated thereunder, and must employ those federal safeguards over the agents they possess and maintain, regardless of whether the mere possession of the agent is itself required to be registered under federal law. The safeguards contained in 42 C.F.R. Part 72 and the Rules promulgated thereunder are adopted herein by reference including subsequent amendments and additions. Copies of this federal provision may be inspected at and copies obtained from the Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915, at a cost of ten cents (\$.10) per page at the time of adoption of this Rule.

History Note: *Authority G.S. 130A-149;*
 Temporary Adoption Eff. January 10, 2002;
 Eff. April 1, 2003.

10A NCAC 41A .0907 RELEASE OF INFORMATION

The Department shall release information contained in the Biological Agents Registry only by order of the State Health Director upon a finding that the release is necessary for the conduct of a communicable disease investigation or for the investigation of a release, theft or loss of a biological agent.

History Note: *Authority G.S. 130A-149;*
 Temporary Adoption Eff. January 10, 2002;
 Eff. April 1, 2003.